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Palliative Care for Patients with Advanced Fibrotic Lung Disease: a randomised controlled phase II and feasibility trial of a community case conference intervention

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Abstract

Background: Those affected by advanced fibrotic interstitial lung diseases have considerable unmet symptom and psychological needs. Case conferencing has been proposed to address these issues, but requires evaluation.
Aim: To obtain preliminary information on the impact of a case conference intervention delivered in the home (Hospital2Home) on palliative care concerns of patients and their carers, and to evaluate feasibility and acceptability.
Methods: Hospital2Home was trialled at a specialist centre using a Phase II fast-track randomised controlled trial with qualitative interviews. The primary outcome for effect was mean change from baseline of Palliative Care Outcome Scale (POS) (a measure of symptoms and concerns) at 4 weeks. Secondary outcomes included symptom control, quality of life, consent and recruitment rates and percentage of patients in the fast-track group receiving case conferences within 14 days.
Results: 53 patients were recruited (26 fast-track, 27 control). Mean (SD) POS scores at 4 weeks were -5.7 (7.5) fast-track vs -0.4 (8.0) control, (mean change difference between the two arms was -5.3 (95% CI: -9.8 : -0.7) Independent t test p=0.02); effect size (95%CI) -0.7 (-1.2 to -0.1). The secondary outcomes of quality of life, anxiety and depression were superior in the fast-track arm, and none were worse. Qualitative findings corroborate these data. Recruitment was successful and 53/67 (79%) of eligible patients consented. 6/25 (24%) had case conferences within 14 days.
Conclusion: Community case conferences improve palliative symptoms and quality of life after 4 weeks. Hospital2Home is feasible and acceptable and now requires testing in further multicentre trials.

What is the key question?

Could a palliative case conference intervention improve palliative care concerns and be feasible in advanced fibrotic interstitial lung disease?

What is the bottom line?

The case conference intervention may improve both patients' and carers' palliative care concerns whilst being both feasible and acceptable.

Why read on?

People living with advanced fibrotic interstitial lung disease experience high levels of unmet palliative care concerns and this work shows that evidenced based palliative interventions such as the case conference can be developed and robustly evaluated to improve and direct care.

INTRODUCTION

Patients with idiopathic fibrotic lung diseases include a large patient sub-group with idiopathic pulmonary fibrosis (IPF), or with alternative diagnoses but an IPF-like outcome.[1] These patients experience substantial unmet symptom and psychosocial concerns that profoundly impact on patients' and carers' lives.[2-4] In addition, poor communication and coordination of care, with little or no discussion surrounding important end of life preferences has been reported.[4]

Recent UK Government legislation promotes better integration of care to improve patient experience and outcomes, providing better continuity of individualised care at the end of life.[5 6] Targeted organisation of care, improved communication and cooperation between disciplines across multiple healthcare settings is required to enable appropriate delivery of palliative care.[7] Case conferencing at the interface between primary and specialist care may deliver individualised holistic care whilst addressing important unmet palliative care concerns.[8-10] Research into case conferences in the non-malignant respiratory setting or centred on the patients' and carers' concerns are absent. In addition, there is a paucity of research developing complex interventions among those with fibrotic lung disease aimed at improving their symptoms and quality of life.[11]

We conducted a phase II feasibility trial of a case conference intervention (Hospital2Home) to obtain preliminary information in what ways Hospital2Home influences the palliative care concerns of patients with advanced fibrotic interstitial lung disease and their carers, and to evaluate the feasibility and acceptability of the intervention in this group.

METHODS

Study Design

A fast-track (wait-list) randomised controlled trial with embedded qualitative interviews were conducted as part of a larger project developing and evaluating Hospital2Home using the Medical Research Council's guidance for developing and evaluating complex interventions.[12] The study was approved by National Research Ethics Service Committee London–Chelsea (ref number:11/LO/0999) and registered on clinicaltrials.gov.uk (NCT01450644). After consent and baseline interview, patients were randomised to fast-track or waiting list groups. For fast-track patients, a Hospital2Home nurse organised a case conference as soon as possible. Waiting list patients were referred for the case conference 4 weeks after randomisation. During the course of the trial, it became apparent that it was extremely difficult to get the case conference for those patients who were randomised to the fast-track group organised within one week and sometimes the waiting list groups' case conference at exactly 4 weeks. An amendment allowed flexibility in the time points of the case conferences and the assessments. Treatment allocation (fast-track/waiting list group) was by computer generated random permuted blocks (by the Institute of Cancer Research) with stratification dependent on severity of patient POS at baseline (patients with a POS score of equal or greater than 28 were classed as severe).

Subjects

Patients with a clinical diagnosis of advanced idiopathic fibrotic lung disease (IPF by American Thoracic Society/European Respiratory Society criteria [13] or fibrotic Non Specific Interstitial Pneumonia) were recruited from the inpatient and out-patient setting in a specialist Interstitial Lung Disease centre (Royal Brompton Hospital, London). Patients included were considered to have end-stage disease clinically (based on clinical status, oxygen requirements and, in some cases, the presence of severe pulmonary hypertension). Where possible, evidence of severe interstitial lung disease was sought, as judged by either High Resolution Computed Tomography (CT) or composite physiologic index scores. Total disease on CT was categorised as limited (< 40%), extensive (>60%) or indeterminate (40–60%). The proportion of honeycombing was recorded as limited (< 15%), extensive (> 35%) or indeterminate (15–35%). Disease was classed as extensive if 1)Extensive disease (>60%) or honeycombing (>35%) on CT or 2)Composite Physiological Index >50. Previous work done by Wells et al [14] has shown a separation in survival between limited (n=36) and extensive (n=100) disease using this classification (HR=5.2 [CI=3.3, 8.1] $p<0.0005$); the latter group (extensive disease) had a 10% survival at two years.

To be included patients and carers had to be >18years old, possess sufficient mental capacity, and able to complete questionnaires in English. Where possible, patient and carer dyads were recruited.

Intervention

All patients received standard best care throughout the study: Patients remained under ILD specialist care for the full duration of the study. This included receiving input from ILD physicians, ILD clinical nurse specialist, occupational therapist, physiotherapist and oxygen assessment and treatment services. In addition, all patients were able to access in-patient ILD treatment as needed. Referrals to community health professionals (as deemed necessary by the ILD team) continued throughout the study. These could include referrals to community nursing (such as community matron or district nurses), respiratory services and community palliative care teams. The Hospital2Home intervention was delivered alongside best standard care (Text Box 1). The fast-track group received the intervention after one week, the waiting list group after four weeks.

Insert text BOX 1 here

Text BOX 1 Hospital2Home intervention

Aims and rationale

The intervention aimed to provide a quality comprehensive palliative care assessment and streamlining of transfer of data between specialist and community settings improving co-ordination of care and communication whilst codifying responsibility for the patient, carer and health professionals. In the UK, a case conference model of care (Hospital2Home) has been used in cancer patients in the acute oncology setting. The Hospital2Home model of care is unique as it has the advantages of a case conference (multi-professional and holistic) and a care plan (care individualised to each patient and carer). The fibrotic ILD Hospital2Home model was developed using Medical Research Council guidance and informed through a systematic review [11] and qualitative interviews.[3-4]

Personnel

Provider: A palliative care specialist nurse delivered the intervention. The nurse had received training on delivery of the intervention from specialist nurses delivering the cancer Hospital2Home intervention.

Supervision: Clinical supervision was provided to assist in identifying and advising on strategies to address problems compromising effective management of the palliative care concerns of these patients and carers. The supervisors met with the nurse approximately weekly and provided additional telephone support as needed.

Attendees: The patient, their carer, Hospital2Home nurse, general practitioner, community matron/district nurse, respiratory nurse and community palliative care nurse (and any other health or social care professional involved in their care or identified as important by the patient) were invited to attend. All patients in the waiting list group who received the case conference had a carer who was present at the case conference. However only 19/25 patients in the fast-track group had carers and only 18 of these attended the case conference. There was consistent representation from community nursing and palliative care teams. However, less than 50% of general practitioners attended the case conferences.

Format

Setting: Case conferences were conducted in the community at a place chosen by the patient (all patients chose their home) Mean (SD) time in minutes taken to organise the case conference for fast-track group 204 (78) range 60-360 and for waiting list group 219 (86) range 60-390

Schedule and duration: 25 patients in the fast-track group and 24 patients in the waiting list group received the case conference. The Hospital2Home nurse contacted patients after randomisation. For patients in the fast-track group where possible, the case conference was organised within one week (6/25 (24%) had case conference within 14 days, median 23 days, range 12 to 51). For patients in the waiting list group, this was organised for 4 weeks time (median 40 days, range 7 to 100). The median length of case conference was 90 minutes in both groups with a range of 60 to 120 minutes in the fast-track and 60 to 150 minutes in the waiting list group. The Hospital2Home nurse followed up the case conferences in each group with the patient/carer via telephone at a 2 week, 1 month and 2 month intervals. Patients and carers were also able to contact the nurse directly as needed for the length of the study. Contacts in addition to scheduled follow up were mean (SD) 49 (78) mins, range 0 to 300 mins for fast-track group and 35 (48) mins, range 0-120 mins for waiting list group.

Content

Prior to the case conference, the Hospital2Home nurse telephoned the patient and carer to identify what their current palliative care concerns were and what they hoped to achieve from the case conference. This included identifying whether patients wished to discuss the sensitive matter of disease progression and planning for the future. During the case conference, which was led by the Hospital2Home nurse, current and anticipated care palliative care concerns were discussed. This included physical, psychological, social and spiritual concerns. In addition, where appropriate, end of life preferences were discussed. Preferred place of care-where the patient wished to be cared for in the last few weeks of life was discussed in 17 (68%) of fast-track and 23 (96%) waiting list case conferences. For 13 (52%) of fast-track and 23 (96%) of waiting list group this was home. Preferred place of death - where the patient wished to die was discussed at 11 (28%) of fast-track and 10 (42%) of waiting list case conferences. Reasons for non-discussion for both preferred place of care and death were patient choice.

An action plan was agreed for each concern discussed at the case conference and a responsible health care professional allocated for each item. Following the case conference, the Hospital2Home nurse with contact details of each health professional, drafted an individualised care plan. The individualised care plan was then communicated to the patient and carer, the ILD specialist team, the general practitioner, all attendees at the case conference and any other health professional identified by the patient as involved in their care. The Hospital2Home nurse would check with the patient/carer at the follow up phone calls that all action points on the care plan had been completed by the allocated health professional. The Hospital2Home nurse aimed to resolve any issues by liaising with the relevant community health professionals.

Delivery

Delivery methods: A collaborative problem solving approach was used whereby the patient and health professionals set agreed goals and jointly developed strategies to achieve them (with advice from the supervisors as needed).

Standardisation: Proformas were used to standardise delivery and general content of the case conference and follow up phone calls and to document issues arising from individual discussions, agreed goals, and difficulties and points for action or discussion at supervisory meetings. Symptom control management was guided by evidenced based guidelines developed during preliminary work (available on request from corresponding author)

Primary outcome

The primary outcome was the Palliative Care Outcome Score (POS). [15] The POS was developed for advanced cancer patients and includes aspects about pain and symptom control, patient and family psychosocial needs, and communication and information needs.[15] The adapted POS used contains eight questions on anxiety, patient and informal caregiver concerns, and practical needs, each rated 0-4. The overall profile score is the sum of the scores from each of the 10 questions and can range from zero to 40. An adapted version which took account of the most common symptoms in this disease group (identified in preliminary work [2 3] was used to provide an assessment of change in palliative care needs (including symptom control).

Secondary outcomes

Secondary outcomes included changes in symptom control and quality of life measures (Table 1). Details of each secondary measures can be located on-line in APPENDIX 1

Table 1 Outcome measures used

BASELINE CHARACTERISTIC/OUTCOME	**INSTRUMENT/MEASURE**
PATIENT	
Patient Palliative Care Needs	Palliative Care Outcome Scale[15]with additional questions for breathlessness, cough, fatigue, insomnia (to be completed by patient and carer)
Patient breathlessness at best/worst	D12 scale[16]
Patient Quality of Life	Kings Brief Interstitial Lung Disease questionnaire [17] and St Georges Respiratory Questionnaire [18]*
Patient functional ability	Medical Research Council breathlessness scale[19]
Patient anxiety	Hospital Anxiety and Depression Scale [20]
Patient use of other services	Service use questions
Preferred place of care and death	
CARER	
Carer Qol	Caregiver Qol Index [21]
Carer anxiety	Hospital Anxiety and Depression scale [20]
Carer's assessment of patient's use of services	Service use questions
Carer burden	Zarit Burden Inventory[22]

* After completion of a background systematic review [11], it was decided to use SGRQ instead of the McGill Quality of Life questionnaire to enable comparison of outcomes with a number of other ILD studies. This amendment was made after recruitment and completion of the first patient in the trial.

Primary and secondary outcome data were collected by postal questionnaire at baseline in both groups. Subsequent time points were 4 and 8 weeks after receiving the intervention in the fast-track group and just before receiving the intervention and 4 weeks after receiving the intervention in the waiting list group. Demographic information was also recorded. Qualitative interviews were conducted after completion of the trial. The topic guide used is depicted in Figure 1.

INSERT FIGURE 1 HERE

Feasibility and acceptability

A-priori criteria for trial feasibility were:

- Consent rate of at least 25%
- Recruitment of 52 patients
- 80% of patients in the fast-track group received their case conference within 14 days of randomisation.

The qualitative interviews were used in the post-trial evaluation to assess acceptability.

Sample size, randomisation and data analysis

52 patients were needed to enable estimation of change in POS score between baseline and 4 weeks with accurate precision (assuming a Standard Deviation of 2, a 95% confidence interval for the difference between the fast-track and waiting list group would be 2.2 units wide i.e. mean difference ± 1.1 units). Anticipated recruitment for qualitative work was 15 (5 patients, 5 carers and 5 health professionals).

We planned an intention-to-treat analysis. The differences in the change in POS scores (baseline to 4 weeks) between the fast-track and waiting list groups were compared using an Independent sample t-test. For all secondary outcome measures descriptive methods were used to report the results in the groups using, mean change scores with SD from baseline to week 4 and effect size at week 4. Only patients with week 4 data were included in change analysis. All quantitative data were analysed using Statistical Package for the Social Sciences (IBM, Chicago, IL).

All qualitative interviews were digitally recorded and transferred verbatim onto a secure transcription database. Analysis was conducted using a constant comparison approach [23] within Framework analysis as described by Ritchie and Spencer.[24] Qualitative analysis was facilitated by NVivo 9. Efforts to maximise analytical rigour included dual coding of a sample selection of the interview transcripts and attention of deviant or non-confirmatory cases.

RESULTS

Patients were recruited October 2011-October 2013 and followed up until December 2013 (when the final patients recruited had completed 8 weeks in the trial) (Figure 2).

INSERT FIGURE 2 HERE.

Baseline measures

Baseline demographic and clinical characteristics for patients and carers are presented in Table 2.

Table 2 Summary table of baseline demographic and clinical data

(Data are means (SD) or numbers (%))

	Fast-track	Waiting List
Patients	N=26	N=27
Age (years)	67.1 (10.9)	70.6 (10.3)
Male	20 (77%)	18 (67%)
Ethnicity		
White UK	21 (81%)	20 (74%)
Black or Black British	1 (4%)	2 (8%)
Asian or Asian British	4 (15%)	5 (18%)
Disease		
IPF	22 (85%)	22 (82%)
NSIP	4 (15%)	5 (18%)
Diagnostic biopsy		
Surgical	8 (31%)	6(22%)
Not carried out	18 (69%)	21 (78%)
% predicted TLCO		
Mean (SD)	25 (10.7)	23 (5.8)
Not carried out	4 (15%)	4 (15%)
Extent of disease on CT		
Limited (<40%)	3 (12%)	3 (11%)
Indeterminate (40-60%)	9 (35%)	14 (52%)
Extensive (>60%)	14 (54%)	10 (37%)
Extent of honeycombing on CT		
Limited (<15%)	10 (38%)	11 (41%)
Indeterminate (15-35%)	11 (42%)	10 (37%)
Extensive (>35%)	5 (19%)	6 (22%)
Composite Physiological Index		
>50	19 (73%)	27 (100%)
Mean (SD)	66.5 (4.0)	64.8 (3.6)
Not carried out	7 (27%)*	0
Using oxygen		
Yes	20 (77%)	23 (85%)
Litres/hr used	3 (1.4)	3 (1.1)
Usage in 24hrs (hrs)	19 (6.6)	21 (5.3)
Co-morbidities		
Yes	17 (65%)	13 (48%)
Heart Failure	1	0
COPD	4	1
Pulmonary Embolism	1	0
TB	0	0
Cancer	1	1
Diabetes	5	4
Other	13	10
Carers	N=19	N=26
Age	61.3 (14.0)	60.3 (13.1)
Male	6 (32%)	6 (23%)
Ethnicity		
White UK	17 (90%)	18 (69%)
Black or Black British	1 (5%)	2 (8%)
Asian or Asian British	1 (5%)	6 (23%)

*3 patients were recruited who had end-stage disease clinically, did not have extensive disease or honeycombing on CT and were too unwell to complete lung function tests.

All analyses was by originally assigned groups.

Primary Endpoint

There was a significantly greater reduction in total POS score between baseline and week 4 for the fast-track group than those in the waiting list group; mean change (SD) -5.7 (7.5) vs -0.4 (8.0) respectively. The mean change difference between the two arms was -5.3 (95% CI: -9.8 : -0.7) independent t test p=0.02; effect size (95%CI) of -0.7 (-1.2 to -0.1) (Figure 3)

INSERT FIGURE 3 HERE

Secondary Outcomes

Patient

For the fast-track group, initial improvements in POS score, King's Brief Interstitial Lung Disease (KBILD) questionnaire, and Hospital Anxiety and Depression (HADs) scores at 4 weeks were all sustained or continued to improve further by week 8 (see Table 5). In contrast these indices did not significantly improve by week 4 for the waiting list group (and actually worsened for POS and KBILD questionnaire scores) but showed significant improvement once the intervention was delivered (i.e. comparison week 4 to week 8). There was also improvement in impact and total scores for St Georges Respiratory Questionnaire (SGRQ) scores in the fast-track group compared to waiting-list group. SGRQ scores for symptoms, impact and total scores also improved in the waiting list group once the intervention was delivered.

Positive effects were identified for patient HADs scores at week 4. This effect was sustained in the fast-track group with continued improvement. There was also improvement in the waiting list group for anxiety, depression, and total scores after the intervention was delivered.

There was no improvement in D12 scores in fast-track group but there was an improvement in D12 scores between week 4 and week 8 in the waiting list group. There was no change in the Medical Research Council scores across both groups over time.

Table 3 Outcome measure data -Outcome data for completed (fully or partial) measures have been presented. All analyses conducted by original assigned groups.

	Fast Track				**Waiting list**				**Effect size (95% CI) at 4 weeks**
	Baseline (mean (SD) or n(%)	4 weeks (mean (SD) or n (%)	Change score Mean (SD)	8 week (mean(SD) or n(%)	Baseline (mean (SD) or n (%)	4 weeks (mean (SD) or n (%)	Change score Mean (SD)	8 week (mean(SD) or n(%)	
Primary endpoint	N=26	N=23			N=27	N=24			
POS	**16.8 (5.6)**	**11.2 (7.9)**	**-5.7 (7.5)**		**17.0 (6.3)**	**16.8 (8.9)**	**-0.4 (8.0)**		**-0.7 (-1.2 to -0.1)**
	The mean change difference between the two arms was -5.3 (95% CI: -9.8 : -0.7) Independent t test p=0.02								
Secondary outcomes									
Patients									
POS				N=19				N=15	
				11.2 (7.3)				12.5 (6.6)	
D12	N=25*	N=22*		N=19	N=27	N=24		N=15	
	22.8 (8.7)	21.6 (10.1)	-0.8 (7.2)	20.4 (9.8)	25.9 (8.2)	25.0 (10.7)	-0.6 (21.3)	21.3 (10.5)	-0.3 (-0.9 to 0.3)
KBILD†	N=26	N=23		N=19	N=27	N=24		N=15	
	35.8 (13.0)	40.0 (16.2)	3.5 (11.0)	43.2 (18.4)	32.3 (12.9)	30.3 (16.2)	-2.6 (21.3)	34.9 (18.0)	0.6 (0.0 to 1.2)
SGRQ	N=25**	N=22**		N=18**	N=26***	N=24		N=15	
symptoms	62.2 (17.7)	62.0 (20.5)	1.4 (16.5)	52 (20.1)	66.3 (24.5)	65.8 (23.0)	-2.0 (23.7)	60.2 (23.8)	-0.2 (-0.8 to 0.4)
activity	88.9 (9.7)	85.3 (17.6)	-3.1 (13.6)	87.1 (10.7)	93.7 (5.0)	92.4 (7.8)	-1.6 (6.8)	91.4 (5.2)	-0.5 (-1.1 to 0.1)
impact	61.6 (18.0)	56.3 (20.3)	-4.0 (19.7)	57.4 (20.8)	71.4 (12.8)	74.8 (14.9)	2.8 (13.3)	62.3 (13.5)	-1.0 (-1.6 to -0.4)
total	70.0 (13.0)	66.0 (16.4)	-2.8(14.9)	65.7 (14.7)	76.8 (10.1)	78.6 (11.8)	0.7 (10.5)	70.8 (10.8)	-0.9 (-1.5 to -0.3)
MRC	N=26	N=23		N=19	N=27	N=24		N=15	
Median	4	4		4	5	5		4	
IQR (25-75)	4-5	4-5		4-5	4-5	4-5		4-5	
HADs	N=26	N=23		N=19	N=27	N=24		N=15	
Anxiety	9.6 (4.6)	8.1 (4.1)	-1.7 (3.3)	7.1 (4.6)	9.7 (5.7)	10.8 (5.5)	1.2 (4.8)	7.9 (5.5)	-0.6 (-1.1 to 0.0)
Depression	9.0 (3.1)	9.4 (3.0)	0.3 (3.2)	8.3 (3.7)	11.0 (4.7)	12.3 (4.8)	1.5 (4.12)	9.3 (4.5)	-0.7 (-1.3 to -0.1)
Total Score	18.6 (6.4)	17.5 (6.3)	-1.4 (5.0)	15.4 (7.7)	20.7 (9.0)	23.0 (9.7)	2.8 (8.1)	17.2 (9.4)	-0.7 (-1.2 to -0.1)
Carers									
POS	N=19	N=15		N=13	N=26	N=22		N=15	
	17.8 (6.5)	14.7 (6.5)	-2.9 (5.8)	16.1 (6.9)	18.5 (6.2)	18.0 (8.4)	-0.7 (9.6)	13.7 (6.3)	-0.4 (-1.1 to 0.2)
ZBI	N=19	N=16		N=13	N=26	N=23		N=16	
	22.2 (15.2)	22.3 (15.3)	0.1 (0.2)	26.2 (13.4)	32.2 (11.7)	31.7 (17.3)	-0.1(0.3)	25.4 (13.4)	-0.6 (-1.2 to 0.1)
HADS	N=19	N=16		N=13	N=26	N=23		N=16	
Anxiety	9.3 (4.3)	8.8 (4.8)	-0.5 (4.8)	9.2 (3.7)	11.0 (5.9)	11.7 (5.6)	0.6 (5.3)	9.8 (4.6)	-0.6 (-1.2 to 0.1)
Depression	7.0 (4.9)	6.4 (4.1)	-0.3 (3.5)	7.0 (4.2)	8.7 (5.0)	9.6 (4.9)	1.0 (4.6)	7.2 (3.9)	-0.7 (-1.3 to 0.0)
Total Score	16.3 (8.7)	15.2 (8.3)	-0.8 (8.0)	16.2 (7.4)	19.7 (10.4)	21.3 (9.9)	1.7 (8.7)	17.0 (8.2)	-0.7 (-1.3 to 0.0)
CQLC†	N=18	N=15		N=13	N=25	N=21		N=13	
Burden	21.9 (8.3)	21.5 (7.1)	-0.6 (6.9)	20.2 (5.7)	25.2 (8.3)	25.2 (8.5)	-0.2 (8.0)	22.1 (9.2)	-0.5 (-1.1 to 0.2)
Disruptiveness	7.8 (6.0)	7.1 (6.9)	-0.6 (4.3)	7.7 (4.8)	9.6 (5.4)	9.3 (5.5)	0.0 (4.9)	7.6 (5.9)	-0.4 (-1.0 to 0.3)
Adaptation	15.6 (5.1)	15.8 (6.1)	0.5 (4.3)	15.9 (5.4)	14.7 (6.8)	14.4 (5.7)	0.1 (5.3)	16.8 (4.2)	0.2 (-0.4 to 0.9)
Financial	2.8 (3.0)	2.5 (3.0)	-0.4 (2.1)	2.4 (3.6)	2.7 (2.9)	2.7 (2.8)	0.3 (2.5)	2.3 (2.1)	-0.1 (-0.7 to 0.6)
Total Score	60.8 (17.4)	58.5 (15.3)	-2.5 (11.0)	58.3 (15.6)	66.7 (16.3)	66.3 (18.4)	0.7 (15.2)	60.2 (23.9)	-0.4 (-1.1 to 0.2)

POS-Palliative Care Outcome Scale, KBILD-King's Brief Interstitial Lung Disease questionnaire, SGRQ-St George's Respiratory Questionnaire, MRC-Medical Research Council Scale, HADs-Hospital Anxiety and Depression Scale, ZBI-Zarit Burden Inventory, CQLC-Carer Quality of life Cancer. Lower scores on the SGRQ and higher scores on the KBILD indicate a better quality of life. † Increase in scores indicates improvement.. *1 patient had greater than 3 items missing on the D12 questionnaire and was therefore excluded as per author's instructions. , ** 1 patient completed McGill quality of life not SGRQ, *** 1 patient removed as greater than 6 items missing on activity SGRQ.

Carer

There was no significant difference in POS scores between the fast-track and waiting lists groups at week 4. However, there was a marked improvement in waiting list scores between week 4 and week 8 (18.0 (8.4) vs. 13.7 (6.3)) respectively. Zarit Burden Inventory score and Carer Quality of Life Cancer burden, disruptiveness, financial and total score followed a similar pattern with no effect of the intervention at week 4. This was followed by improvement in scores between week 4 and week 8 in the waiting list group.

There were borderline effect sizes of the intervention on depression and total HADs scores (-0.7 (-1.3 to 0.0) and -0.7 (-1.3 to 0.0) respectively). This was followed by improvement between week 4 and week 8 scores for the waiting list group for anxiety (11.7 (5.6) vs. 9.8 (4.6)), depression (9.6 (4.9) vs. 7.2 (3.9)) and total score (21.3 (9.9) vs. 17.0 (8.2)) respectively.

Data related to study

As of study close on 31/12/2013, a greater number of waiting list patients (13 (54%)) had died than Fast-track (8 (32%)). Preferred Place of Care and Preferred Place of Death were less likely to be achieved for patients who died in the Waiting list group; Preferred Place of Care: FT 8 (100%) vs. WL 11 (84%), Preferred Place of Death: FT 7 (88%) vs. WL 10 (77%). More patients died at home in the fast-track group; FT 5 (62%) vs. WL 5 (38%) and in hospital in the waiting list group; FT 1 (12%) vs. WL 5 (38%). All 3 patients who died before being able to receive the case conference were in the waiting list group and all died in hospital.

Qualitative findings

APPENDIX 2 shows the qualitative participants' characteristics. Key quotes are presented in Table 6 and the full qualitative findings can be found in APPENDIX 2.

Table 4 Presentation of qualitative findings (all names have been changed to ensure confidentiality)

Theme	Participant	Example quote
Support in the community	Ann, 72 year old wife of Stephen who had advanced NSIP	"I was bit nervous before hand you didn't have anyone to turn to really…..we have one son in xxxx but he's far away and (2) I have a sister in xxxx which phones me up every day but [coughs] otherwise that's I felt alon:::e" "and how do you feel now?" (SB) "I feel better……. 'cause I have all the phone numbers and people phone me up…."
Individual care plans and practical problems addressed	Community palliative care CNS	"[the H2H CNS] contacted us afterwards to check everything we had said we were going to do we'd done which we had erm::: and we had her number to be able to contact if he had any problems as well so::: erm it went all quite smoothly really…"
Co-ordination of care and efficiency	GP	"if it wasn't for this (2) I can see a completely different scenario where this guy would be lost in the community ….he::: would be trying to find out who::: the respiratory nurse is [laughs] trying to get out who's the oxygen supplier trying to find out from his GP which one's going to be in charge of his care in the general practice which one's going to be helping him with his symptoms (1) you know it it would have become a hug:::e hassle and I don't think he::: realises how lucky he is actually to be part of this trial (2) because everything's there for him (2) there's no other issue…"
Crisis management	Peter, 63 year old with advanced IPF	"and now I've got all erm (2) they as I say they phone and I've got er a whole list of numbers that I can phone any time day or night erm if I need to, you know….oh yes yeah and (1) and (2) as I say I've got erm the telephone numbers… of of people that I can phone erm 24 seven which is ideal I mean before that erm the most I could do was dial 999"
Palliative Care, psychological support	Ted, 55 year old patient with advanced IPF	"I must say to everybody (2) definitely it is it it's (2) I don't know how long I've got left but (2) whatever time I've got left (3) this palliative care is going to make that time better for me and it's better and if it's better for me it's better (2) for us as a family….I've been telling everybody (2) how important (3) you know I just wish I could get GPs in to buy into the (2) palliative care cause its makes such a difference (2) made such a difference to me…… I I have weeks when (2) er like last week I wanted to talk about (3) you know (2) my illness and stuff…and they're there then (2) for me to be able to tap into.. which I am happy for because (3) when you're in in my my sort of position when you know your life limited (1) is your life is limited often at home (3) you tend you live a lie say to people you live a lie I think because say how do you feel you just say I feel fine but because you don't want to be worrying people all the time but (1) when you've got a palliative care team round you you can get that out of your system which is something we didn't have for the first 18 months two years of this disease"
Symptom control	ILD CONSULTANT	"we would star:::t er symptom control in hospital whether that was a little bit of Oramor:::ph or lorazep:::am and then it was really we wouldn't often see the patient for another 3 or 4 months time and it was then back to the GPs han:::ds to sort of titrate and change that as needed um and it it didn't always go successfully the things weren't re-prescrib:::ed or wrong doses were given but knowing that er (1) you and your team are now doing that again we've had patients say that it's been very useful for them to have sort of continuity of care and someone taking overall view of that…."
Empowering HP	ILD CNS	"it's certainly enhanced my practice, um, certainly there's an huge (1) element of my job which is dealing with um the palliative care and end of life of patients, and I think, seeing how palliative care interact with patients and bring up (1) uncomfortable::: (2) subjects for us as health care professionals, certainly has enhanced my practice….We need to::: (1) understand that these aren't necessarily subjects that patients don't want to discuss…sometimes some of the anxiety around the issues can be discussing what the future is, discussing, (1) you know, having those uncomfortable conversations. I think, H2H has facilitated that, helped patients be more organised and think around what they're doing and also highlighted to us how to go about those conversations, and that those conversations are (1) ok to have."
Advance care planning	Leslie, 54 year old wife of Ted who had advanced IPF	"for us it was a bit traumatic you know everything being coming to life that actually these things are happening I think you can go to hospital appointments and still sort of brush it aside that you know [laughs] erm (2) but once everybody was sat round the table and we talked about DNRs …and erm (4) advanced directives and all this sort of stuff it did bring it home and it did get a little bit (3) upsetting but (3) I I still do believe that it was better at that point than when (1) somebody's actual laid on their bed and you think it could be any da:::y and (2) erm (1) you know I think you can deal with it better at that stage"

DISCUSSION

This fast-track randomised controlled trial of a case conference intervention in advanced fibrotic ILD patients and carers identified an improvement in both symptom control and quality of life. Of note, there was no worsening of any outcome after receiving the intervention. This suggests that no harm and potentially a prevention of deterioration may have occurred. Mean change difference scores in POS scores in the fast-track group were 5.7 points at 4 weeks, sustained at 8 weeks. For the POS, a variation of one point in individual items is linked to clinical meaningful change.[15] There was also a promising large effect size. Similar improvements in the waiting list POS scores once they received the intervention suggest that the intervention may improve the palliative care concerns of these patients. Use of evidenced based guidelines and a comprehensive palliative care assessment at the case conference, on-going palliative care involvement and/or added time with care providers may have contributed to this.

Baseline scores showed that patients were living with poor quality of life. Improvements were observed in both the KBILD and SGRQ impact and total scores at week 4 in the fast-track group. The improvement in the waiting list SGRQ impact and total scores were marked between week 4 and week 8 where both domains showed improvement greater than the Minimal Important Clinical Difference (MID) for IPF. Improvements were also identified in anxiety and depression scores. Of note, baseline mean patient anxiety and depression scores and mean carer anxiety scores in both groups were borderline abnormal or abnormal. Importantly, the waiting list group showed deterioration for all anxiety and depression scores in both the patients and carers during the 4 week wait. However, this improved after receiving the intervention. Clinically meaningful improvements in HADs scores of both

patients and their carers (The MID in COPD is 1.5 [25]) were identified. These improvements find correspondence with the qualitative interviews. Before the case conference, patients and carers stated they had very little knowledge of support they were entitled to and were suffering alone. Through the case conference, patients and carers had access to specialist community palliative care services that routinely support patients' and carers' holistic palliative care concerns. Patients and carers reported being less anxious from being linked in to community services. Moreover they were grateful for the clear crisis management strategy provided through the individualised care plan. Both patients and carers interviewed valued the case conference itself as they felt that it "laid everything on the table" and importantly addressed concerns and anxieties that had been playing on patients' and carers' minds. This supports findings by Lindell et al who evaluated an interventional disease management programme in IPF and Higginson et al's [26] recent trial of a breathlessness intervention service among 105 patients with refractory breathlessness (including ILD patients). Both observed improvements in psychological symptoms.

Hospital2Home aimed to facilitate early discussion about disease progression, to improve communication and address end of life planning needs. Not all patients wanted to talk about advance care planning decisions such as preferred place of care and preferred place of death. This was similarly identified by Abernethy et al [10] where prognosis, end of life issues, and previous experiences of death were rarely discussed at the case conference for cancer patients. For those patients in this trial who did discuss advance care planning, even though it could initially be distressing for relatives, it was seen as incredibly useful. For some patients, the case conference provided them with permission to conduct these important conversations. Interestingly, patients who did not want to discuss advance care planning at the case conference then went on to have subsequent discussions with their community health professionals. This may have been precipitated by those initial discussions by the

Hospital2Home nurse and the development of relationships with the community palliative care team after the case conference. For patients who wished to discuss preferred place of death, no patients reported hospital as their preference. The actual place of death for patients having received the case conference was hospital in only 28% of patients. This is much less than observed in a retrospective case note review [2] where 76% of advanced fibrotic ILD patients attending two acute hospitals died in hospital. Interestingly, the 3 patients who died in the waiting list group before receiving the intervention; all died in hospital. Patients with IPF experience increased healthcare resource utilisation, and direct medical costs.[27] This is important at the end of life. It is possible that the case conference, through documenting end of life preferences, establishing links in the community setting, and preventing crisis admissions enabled patients not to die in hospital. The economic impact of this requires further investigation.

The fast-track study design worked effectively and is likely to be an influencing factor as to why consent and recruitment rates were met as all patients received the intervention. However, only 24% of the fast-track group received the case conference within the *a-priori* 14 day allotted timeframe. Health professionals were often unable to schedule a case conference within one week's notice. This has been found previously; Abernethy et al [10] observed that only 38/167 case conferences in their trial were held within 28 days. When considering the waiting list period, 4 weeks was chosen as this was considered long enough to identify an effect of the intervention on the primary outcome, but not result in a high rate of attrition due to death. However, as only a small number of patients (3/27) did not receive the case conference intervention as they died before 4 weeks, this time period could be extended in any future phase III study allowing health professionals in the fast-track group adequate advance notice to attend a case conference.

Patients, carers and health professionals alike praised the Hospital2Home model of care. General Practitioners have previously reported that a case conference allows them to be better informed, makes discharge planning easier and gives clear delineation of role between primary care and specialist services [28], findings supported by this trial. However, compared to cancer patients, fewer General Practitioners attended the case conferences (less than a third in the fast-track and less than 50% in the waiting list group; 100% for cancer patients). Further, in some instances community palliative care declined referrals despite clear explanations of the nature of the study and patients' palliative care needs. This is likely to reflect the lack of understanding amongst community health professionals of the terminal nature of advanced idiopathic fibrotic lung diseases and their associated palliative care needs. This requires on-going education. The qualitative work also identified lack of early referral to palliative care by community health professionals, despite requests from patients and carers, and some gatekeeping by hospital health professionals. It is clear that there is still a mis-conception that palliative care is a last resort and referral should only be made at the end of life. This exists in spite of the World Health Organisation's advice that palliative care should be delivered in parallel to active care once a life-limiting illness has been identified. Recommendations of the British Thoracic Society [29] and NICE [30] support this; palliative care teams should be involved in IPF patient management to ensure adequate symptom control and psychological support. If palliative care is only delivered at the end of life, patients and carers may be denied valuable symptom control and psychosocial support in earlier stages of the disease and important decisions around end of life preferences may not be identified and acted upon. Strategies on improving the knowledge of patients, carers and health professionals on the benefits of early palliative care need to be explored.

The recent NICE guidance for IPF has stated that the ILD specialist services ought to able to manage the palliative care needs of patients and to refer to the appropriate community

services.[30] In addition, only patients whose palliative care concerns cannot be met by the ILD services ought be referred to specialist palliative care services.[30] However, despite involvement of specialist ILD services, patients and carers continue to have unmet palliative care concerns and limited community support.[3] In reality, the pressure of busy ILD clinics is likely to mean that concerns are not assessed and remain neglected. Hospital2Home may enable these concerns to be examined and managed through an individualised care plan whilst facilitating development of important relationships with community health professionals.

There are a number of limitations to this trial. POS has not been validated in ILD. However, no other holistic palliative care measures have been either. This phase II trial was not adequately powered to identify efficacy therefore results must be interpreted with caution. Despite this the trend towards positive differences between groups was observed and strongly suggests a further adequately powered study that is informed by the learning from this study. Referrals to community services for the waiting list group were made at randomisation and beyond the control of the study, a few community services contacted patients and carers before the case conference. This coupled with the delay in delivering the case conference to the fast-track group may have affected comparison of the efficacy of the intervention at the primary endpoint of 4 weeks. However, these factors are likely to have under-estimated rather than over-estimated any effect. The HRCT/CPI criteria for excluded patients were not recorded which may have provided valuable clinical information. The Hospital2Home intervention is a complex intervention with multiple different components. Attempts were made to standardise delivery as much as possible with proformas and evidenced based guidelines. Despite this, there is likely to have been some variance in delivery. Due to constraints of the study, outcome measures were not collected after the 8 week mark. This may have provided valuable information of possible effects of the intervention over time.

Conclusion

Preliminary evidence from this trial reveals a positive effect on both patients and carers of the Hospital2Home intervention on palliative care concerns, quality of life and anxiety and depression. In addition, the intervention managed uncertainty by facilitating early discussion about disease progression, improving communication and addressing end of life planning needs. The Hospital2Home intervention therefore appears to be feasible, acceptable and effective across a number of domains.

As this is a phase II study, any positive effects may be promising but would need to be further examined in a multicentre phase III study before conclusions about wider effectiveness may be drawn. Despite this, the information obtained from this trial will allow sample size calculation in future studies, has provided valuable information on the spectrum of concerns of patients and carers affected by advanced idiopathic fibrotic ILDs, the potential effects, feasibility and acceptability of the Hospital2Home intervention in this group.

Contributions

JR conceived the study and secured funding. SB, JRR, AUW, KM, SBi, ASP, IJH and JR contributed to the design of the study. SB and CO conducted the study. JRR supported the day to day running of the study. SB completed all quantitative and qualitative analyses. KM supported all quantitative analysis. JK supported all qualitative analysis. SB drafted the paper. JRR, AUW, KM, CO, SBi, ASP, JK and IJH edited and revised the paper critically for important intellectual content. SB, JRR, AUW, KM, CO, SBi, ASP, JK, IJH and JR approved the final version to be published.

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Competing interests

No authors had any competing interests

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